Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children

Protocol summary

Summary

How to implement the plan: This study is a clinical trial and designed to investigate the effect of anti-pronation static splint on activities in 10 spastic hemiplegic cerebral palsy children with 8-12 years old. Two groups are participated in this study; an intervention group (N=10) and a control group (N=10). The patients who have inclusion criteria: 8-12 years old spastic hemiplegic cerebral palsy children; classification of 2 and 3 Gross Motor Function Classification System (GMFCS) selected randomly from therapeutic centers of Tehran. Exclusion criteria: Non-cooperation; Patients should fill the consent form and demographic questionnaire before starting the assessments. Assessments include box and block test, passive range of motion of elbow extension, forearm supination and wrist extension with goniometry, severity of spasticity with Modified Ashworth Scale, and performance of activities with Activities Scale for Kids. Colleague of examiner does the assessments in intervention and control group (10 children) and records the data. After the preliminary assessments, patients are divided into intervention and control groups. Masters will check groups with regard to severity of spasticity, level of performance, age, gender and homogeneity. In order to make of anti-pronation static splint, patients of intervention group are introduced to the research and therapeutic hand clinic in school of rehabilitation of Tehran University of Medical Sciences. After fabrication of positive mold, pattern of splint is cropped on thermoplastic material. This material is heated and placed on the positive mold and covers forearm from distal crease of ulnar side of wrist to two-thirds of upper forearm. Dorsal side on distal head of ulna is a landmark for producing a puncture. From this point a strip passes and a ring is clinched to the end of the strip. In order to prevent of pressure on the head of ulna, the pads put inside the splint and place it on the patient forearm so that the strip starts from distal and dorsal side of wrist, passes inside of splint , stands on volar side of wrist then passes from the ring and ends on velcro of palmar side of splint. Also another strip is prepared for stabilizing splint on forearm. Duration of therapy is 8 weeks and the splint should be used6- 8 hours during a day. The patients are trained on how to use and keep the splint. After 8 weeks of application of splints, assessments are repeated by colleague of examiner and the results will be analyzed statistically. Examiner colleague is blinded about the patients in intervention and control groups. During the intervention time, patients in intervention and control groups benefit from conventional treatments of occupational therapy such as Neurodevelopmental Treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042717450N1**
Registration date: **2014-07-02, 1393/04/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-07-02, 1393/04/11

Registrant information

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Recruitment status

Recruitment complete

Funding source
Tehran University Of Medical Sciences

Expected recruitment start date
2014-07-23, 1393/05/01
Expected recruitment end date
2014-09-23, 1393/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children

Public title
Study of effect of anti pronation static splint on activities in 8-12 years old spastic hemiplegic cerebral palsy children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 8-12 years old spastic hemiplegic cerebral palsy children; classification of 2 and 3 Gross Motor Function Classification System (GMFCS) exclusion criteria: Non-cooperative
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Draw

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences Ethics Committee
Street address
Tehran University of Medical Sciences , Enghelab Av, Tehran, Iran,
City
Tehran
Postal code
Approval date
2014-06-09, 1393/03/19
Ethics committee reference number
93-01-32-25272-112535

Health conditions studied

1

Description of health condition studied
spastic hemiplegic cerebral palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Activities Scale for Kids
Timepoint
monthly
Method of measurement
questionnaire

Secondary outcomes

1

Description
Function
Timepoint
Monthly
Method of measurement
Box and Block Test and Activities Scale for Kids

Intervention groups

1

Description
Control group :conventional treatments
Category
Rehabilitation

2

Description
Intervention group : Anti Pronation Static Splint
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation Centre
Full name of responsible person
Mehdi Abdolvahab
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City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Dr Masuod Uonesian
Street address
Tehran University of Medical Sciences , Enghelab Av, Tehran, Iran,
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty